

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and these remarks.

### **I.      Status of the Claims**

Claims 3, 5 and 7-19 were cancelled previously. Claim 20 has been revised, without prejudice or disclaimer, to delete the recitation of hybridoma FERM BP-7840. Claims 1, 2, 4 and 6 are withdrawn for recitation of non-elected species. Applicants respectfully request that claims 1, 2, 4, and 6 be rejoined for examination upon allowance of a generic claim.

Because no new matter is introduced, applicants respectfully request entry of this amendment. Upon entry, claims 1, 2, 4, 6 and 20-25 will be pending.

### **II.     Rejection of Claims under 35 U.S.C. §102(b)**

The examiner maintains the rejection of claims 23-25 for alleged anticipation by PCT Publication WO/01/66596 by Itoh *et al.*, as evidenced by Yu *et al.*, *Endocrinology* 146: 4647-56 (2005), and Mohammadi *et al.*, *Cytokine Growth Factor Rev.* 16: 107-37 (2005). In particular, the examiner contends that Itoh's antibodies have "antagonizing FGF-23 activity" (Office Action, page 3, line 29) (i) because, according to the reference, the antibodies can be used to prevent or treat diseases involving overexpression of the FGF-23 and (ii) because Itoh allegedly discloses that the antibodies "block FGF-23 activity, for example in a bioassay (see Itoh, in particular page 30, 4<sup>th</sup> to 5<sup>th</sup> paragraphs and page 31, 1<sup>st</sup> -3<sup>rd</sup> paragraphs)." Office Action, page 3, lines 23 & 24.

Applicants respectfully disagree and, therefore, traverse this rejection. In fact, Itoh *prophesizes* that antibodies, in principle, can be made from fragments of FGF-23, but there are no working examples to show that polyclonal or monoclonal antibodies, if produced as proposed, would have a given specificity or would recognize a given epitope.

By contrast, the present application documents various monoclonal antibodies against FGF-23. Thus, Example 27 demonstrates that, among the antibodies tested, those produced by hybridomas FERM BP-7838 and FERM BP-7839 possess the activity of increasing phosphate in a mouse model, while antibody produced by hybridoma FERM BP-7840 and antibody 2A2B fail to increase phosphate in the mouse. Accordingly, not all antibodies that can bind to FGF-23 have the activity of neutralizing the FGF-23 activity; hence, obtaining an antibody with such activity is not a necessary (*i.e.*, an “inherent”) outcome of following the prophetic agenda for research that Itoh memorializes.

According to the examiner, “it is applicant’s burden to show that the reference antibodies are not competitive with the instantly claimed antibodies” (Office Action, page 4, lines 7-8). In the first instance, however, it is impossible to test “Itoh’s antibodies” as a practical matter, since the reference actually fails to identify an actual antibody that might be tested for competitive binding. As a matter of law, moreover, the “fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” MPEP § 2112, IV (original underscoring; citations omitted). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Id.*, quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

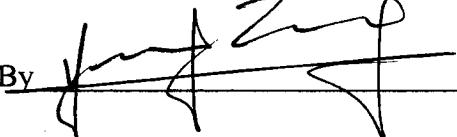
The burden is with the examiner, therefore, to substantiate the proposition that Itoh necessarily places with the knowledgeable reader an antibody, per claim 23, that not only is “competitive with the antibody produced by a [recited] hybridoma” but that also “can neutralize ... FGF-23 activity.” Since not all anti-FGF-23 antibodies possess this activity, as applicants have shown, it follows that the examiner cannot rely on Itoh’s general, prophetic disclosure to sustain his burden in this context. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

## CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Skelding is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

By 

Stephen A. Bent  
Registration No. 29,768  
By Yang Tang  
Registration No. 55,663

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FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399